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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,514	03/10/2004	Elmar Kraus	14503-003001 / F62554US	4007

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FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
KIM, SUN U	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/797,514	KRAUS ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *19-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 41-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 19-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/10/06.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 11-18 and 41-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al (US Pat. No. 5,744,042) in view of Ohmura et al (US Pat. No. 5,440,018). Stange et al teach a method for dialysis or the separation of protein-bound substances from a protein containing liquid e.g. blood or plasma comprising a first dialysis step in which a protein containing liquid e.g. blood or plasma is dialyzed against a dialysate liquid across a membrane wherein human serum albumin (HSA) or recombinant human albumin are present in the dialysate liquid and/or attached to at least one side of the membrane and membrane has two functionally different parts, one part having the actual separating membrane and the other part

having a port and adsorption function and the membrane coated with human serum albumin or recombinant human albumin (see abstract; col. 6, lines 23-67)(Claims 1, 15, 18, 41, 43, 50-51, 53-59). Regarding claims 16-17, Stange et al teach that HSA in the dialysate liquid is in a concentration of about 10% to about 20% by weight of the dialysate liquid (see col. 10, lines 27-31). Regarding claims 45-47, Stange et al teach that the tunnel-like structure of the actual separation membrane having the tunnel length less than about 0.1 micron and having a diameter sufficiently small to exclude protein in blood or plasma (see col. 10, lines 33-52). Regarding claims 48-49, Stange et al teach that the membrane material is a polysulfone (see col. 11, lines 7-21). Regarding claims 52 and 64-66, Stange et al teach that HSA in dialysate liquid is in a concentration from about 1 to about 50 g/100ml, from about 6 to about 40 g/100ml, from about 8 to about 30 g/100ml, or from about 8 to about 20g/100ml (see col. 9, lines 30-41). Stange et al does teach the use of recombinant HSA (see col. 6, lines 45-48). Regarding claim 60, Stange et al teach that, after the first dialysis step, dialysate liquid (B) is passed through a second conventional dialyzer to dialyze against aqueous standard dialysate liquid (see col. 13, lines 51-60). Regarding claim 61, Stange et al teach that, after the first dialysis step, the dialysate liquid (B) is passed through a charcoal-adsorbent and an anion exchange column (see col. 13, line 61 – col. 14, line 4). Claims 1, 15-18, 41, 43 and 45-66 essentially differ from the method of Stange et al in reciting the recombinant HSA has been purified from accompanying fatty acids prior to the first dialysis step. Ohmura et al teach a recombinant HSA purified from fatty acids by chelate resin treatment to yield a substantially pure form of recombinant HSA (see col. 1, lines 7-12; col. 8, line 63 – col. 9, line 38). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use substantially pure form of recombinant HSA

purified from fatty acids in the method of Stange et al for effective dialysis and separation of protein-bound substances from blood or plasma because purified recombinant HSA has binding affinities that are equivalent to plasma proteins as suggested by Ohmura et al (see col. 18, lines 9-27). Regarding claims 2, 42, 44 and 62-63, Ohmura et al teach that HSA obtained through ultrafiltration, heat treatment, acid treatment and another ultrafiltration, followed by subsequent treatments with a cation exchanger, a hydrophobic chromatography carrier and an anion exchanger, and by salting out contains no proteinous and polysaccharide contaminants (see abstract; col. 2, lines 10-64; col. 10, lines 29-42). Regarding claims 11-12, Ohmura et al teach that HSA is precipitated from a solution containing recombinant HAS (see col. 7, lines 48-55). Regarding claims 13-14, Ohmura et al teach cation and anion exchange and hydrophobic chromatography for purifying recombinant HSA (see col. 2, lines 39-50).

4. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al in view of Ohmura et al as applied to claims 1-2 above, and further in view of Fulton (US Pat. Application Publication No. US 2003/0036637 A1). Stange et al in view of Ohmura et al teaches a dialysis method and separation of protein bound substances using purified recombinant HSA as described in above paragraph 3. Claims 3-7 essentially differ from the method of Stange et al in view of Ohmura et al in reciting that recombinant HSA is from the milk of lactating bovine (claims 3-6) or from an egg of a transgenic bird (claim 7). Fulton teaches the purified recombinant HSA from milk of transgenic non-human animal including cow i.e. bovine and egg of a transgenic bird including chicken (see paragraph 0005, 0011). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute recombinant HSA from the milk of transgenic non-human animal including cow i.e. bovine and

egg of a transgenic bird including chicken for the purified recombinant HSA as an alternative source of recombinant HSA in the method of dialysis and separation of protein bound substances of Stange et al in view of Ohmura et al.

5. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al in view of Ohmura et al as applied to claim 1 above, and further in view of Kadima et al (US Pat. Application Publication No. US 2005/0282734 A1). Stange et al in view of Ohmura et al teaches a dialysis method and separation of protein bound substances using purified recombinant HSA as described in above paragraph 3. Ohmura et al teach a recombinant HSA purified from fatty acids by chelate resin treatment to yield a substantially pure form of HSA (see col. 1, lines 7-12; col. 8, line 63 – col. 9, line 38). Claim 8 essentially differs from the method of Stange et al in view of Ohmura et al in reciting that the recombinant HSA has been purified from accompanying fatty acids by the use of activated charcoal. Kadima et al teach that fatty acids are removed from HSA by passing it through a charcoal pad (see paragraph 0204). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to remove fatty acids from the recombinant HSA by the use of activated charcoal instead of chelated resin to obtain a purified recombinant HSA used in the method of dialysis and separation of protein bound substances of Stange et al in view of Ohmura et al. Regarding claims 9-10, Ohmura et al teach the step of ultrafiltration of a culture supernatant for inherent clarification of recombinant HSA containing solution (see col. 5, lines 28-47).

6. Applicant's arguments with respect to claims 1-18 and 41-60 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Stange et al teach the use of recombinant HSA in the dialysate liquid (see col. 6, lines 45-48). Ohmura et al teach the purified recombinant HSA from accompanying fatty acids (see col. 1, lines 7-12; col. 8, line 63 – col. 9, line 38). Applicants argue that the removal of fatty acids from recombinant HSA does not appear to be a major concern to Ohmura et al. However, Ohmura et al teach the removal of fatty acids via chelate resin treatment to purify recombinant HSA (see col. 8, line 63 – col. 9, line 38). Applicants further argue that Ohmura et al further suggest at col. 4, lines 47-48 to add fatty acids to the cell medium during albumin production. Such step is for the production of albumin and not a purification step of recombinant HSA where

fatty acids are, in fact, removed from recombinant HSA as described in Ohmura et al (see col. 8, line 63 – col. 9, line 38).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. This application contains claims 19-40 drawn to an invention nonelected with traverse in the reply filed 4/10/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John Kim
Primary Examiner
Art Unit 1723

JK
November 27, 2006